UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,788	01/06/2000	THOMAS JOHN BALDWIN	5673-53922	1383

7590 06/26/2003

WILLIAM D NOONAN
KLARQUIST SPARKMAN CAMPBELL LEIGH & WHINSTON
121 SW SALMON STREET SUITE 1600
ONE WORLD TRADE CENTER
PORTLAND, OR 97204-2988

EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	20

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/445,788	Applicant(s) Baldwin et al.
	Examiner Jennifer Graser	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5-48 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-5-48 are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 25-27 and 45, drawn to a vaccine composition comprising antigenic material selected from (I) an attenuated live mutant bacterium having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene product is regulated independently of the iron concentration in the environment of the bacterium and (ii) a non-viable preparation comprising bacterial membrane antigens from cultured cells of a mutant bacterium having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene product is regulated independently of the iron concentration in the environment of the bacterium and a pharmaceutically accpetable carrier and a method of treating a subject using said bacterium.

Group II, claim (s) 28-41, drawn to an attenuated bacterium having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene product is regulated independently of the iron concentration in the environment of the bacterium. **NOTE:** Applicants

must elect a specific attenuating mutation, i.e., one of the *aro* genes, one of the *pur/pyr* pathway genes.

Group III, claim (s) 42-43, drawn to an attenuated mutant *N.menitigiditis* strain. **NOTE:** Applicants must elect a single genotype in claim 42 (a), (b), (c) or (d).

Group IV, claim (s) 44, drawn to a preparation of membrane vesicles.

Group V, claim (s) 46, drawn to a method of manufacturing a vaccine composition.

Group VI, claim (s) 47-48, drawn to a method of producing an attenuated bacterium having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene product is regulated independently of the iron concentration in the environment of the bacterium. **NOTE:** Applicants must elect a specific mutation in claim 48.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a vaccine comprising a non-viable preparation comprising bacterial membrane antigens from cultured cells of a mutant bacterium having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene product is regulated independently of the iron concentration in the environment of the bacterium. Methods of using this vaccine are also included in the Group. This is a different product than is recited in Group II. The special technical feature of Group II is an attenuated bacterium having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene

product is regulated independently of the iron concentration in the environment of the bacterium. This special technical feature is structurally and biologically different from that of Group I because the special technical feature of Group I is non-viable and made up of antigens whereas the special technical feature of Group II is an attenuated (live) whole cell. The special technical feature of Group III is an attenuated mutant *N.menitigiditis* strain with specific genotypes and including a *minB* mutation, an RTX negative phenotype and/or an *opc* gene mutation. This bacterium is biologically and structurally different than the bacterium of Group II. The special technical feature of Group IV is membrane vesicles. The special techinal feature of Group V is a method of manufacturing a vaccine which is different from the vaccine recited in Group I, i.e, whole cell versus non-viable membrane antigens. The special technical feature of Group VI is a method of producing an attenuated mutant bacterium which is different than the non-viable membrane antigens recited in Group I. Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features .

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A. A mutation in the aro genes or the pur/pyr pathway genes (if Groups II, V or VI are elected)

B. Parts (a)-(d) of claim 42. (If Group III is selected, must choose between (a)-(d).)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

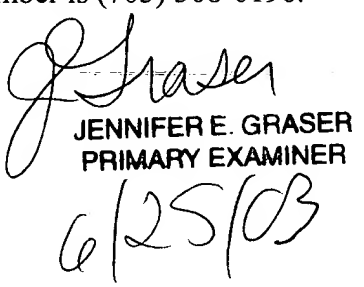
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JENNIFER E. GRASER
PRIMARY EXAMINER
6/25/03